TUESDAY, MARCH 10:
TRACKING & TRACING THE DRUG SUPPLY CHAIN
WELCOME

Anthony Pudlo, PharmD, MBA, BCACP
Vice President, Professional Affairs Iowa Pharmacy Association
PRESENTERS

Michael Keegan
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NCPA

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ASHP

Scott Mooney
VP, Distribution Operations
McKesson Pharmaceutical
Drug Supply Chain Security Act

Michael Keegan, NCPA Policy and Regulatory Affairs
March 10, 2015
Drug Quality and Security Act

• The Drug Quality and Security Act was signed by the President on November 27, 2013.
• Contains two main “titles”:
  – Title I Drug Compounding: establishes national standards for compounding pharmaceuticals
  – **Title II Drug Supply Chain Security Act (DSCSA):** establishes a national system for tracing pharmaceutical products through the supply chain, sets national licensing standards for wholesale distributors and third-party logistics providers, and preempts existing state licensing and pedigree requirements.
Drug Supply Chain Security Overview: 3 parts

1. **Traceability**: Establishes a two phased national system for tracing pharmaceutical products through the supply chain.

2. **Licensing**: Establishes uniform national licensing standards for wholesale distributors and third-party logistics providers.

3. **Preemption**: Immediately preempts all state laws and regulations for tracing products through the supply chain (i.e., pedigree requirements) AND state laws and regulations regarding wholesale distributor and 3PL licensure.
1. **Traceability**: Establishes a two phased national system for tracing pharmaceutical products through the supply chain.

2. Licensing: Establishes uniform national licensing standards for wholesale distributors and third-party logistics providers.

3. Preemption: Immediately preempts all state laws and regulations for tracing products through the supply chain (i.e., pedigree requirements) AND state laws and regulations regarding wholesale distributor and 3PL licensure.
The traceability requirements in Phase 1 and 2 apply to PRODUCTS.

- Products = prescription drugs in finished dosage form that are for human use.
- no OTC, medical devices, API, or drugs indicated for animal use

A number of prescription drugs are exempted from the definition of product, including:

- Blood and blood components intended for transfusion
- Radioactive drugs and radioactive biologics
- Imaging drugs
- Intravenous products
- Medical gases
- Homeopathic drugs
- Compounded drugs
The traceability requirements in Phase 1 and 2 apply to TRANSACTIONS.

- Transaction = changes in ownership.

A number of transfers are exempted from the definition of transaction, including:

- Transfer of a product from one pharmacy to another (regardless of whether the two pharmacies are affiliated in any way) to fill a prescription for an identified patient.
- Distribution of minimal quantities of products by a licensed retail pharmacy to a licensed practitioner for office use.
- Distribution of a product pursuant to a sale or merger of a pharmacy or WD.
- Distribution of combination products (device + drug/device/biologic).
- Distribution for emergency medical reasons.
Part 1: Traceability

Establishes a two phased national system for tracing pharmaceutical products through the supply chain

a) Phase 1: Product tracing – supply chain partners pass transactional data to subsequent purchasers (data exchange occurs with change of ownership only).

b) Phase 2: Product identifier – supply chain partners trace product identifiers thru the supply chain.
Phase 1

- Starting January 1, 2015:
  - Manufacturers are required to pass *transaction data* to subsequent purchasers.
  - Repackagers and wholesale distributors will be required to receive *transaction data* from manufacturers and pass *transaction data* to subsequent purchasers.

- July 1, 2015: dispensers are required to receive *transaction data* and pass *transaction data* if they further distribute
What is “transaction data” that must be passed, received, and maintained by supply chain participants?

Three items:

• transaction information
• transaction history
• transaction statement

– These include information about the product and transaction (TI), the seller’s compliance (TS), and the subsequent owners & transactions (TH).
On December 24, 2014, the FDA announced that it will exercise its discretion not to enforce the product tracing requirements of the DSCSA until May 1, 2015.

Unclear whether FDA will delay this requirement for dispensers as well, but the agency is expected to.

The enforcement discretion does not apply to other requirements in the DSCSA that took effect on January 1, such as trading partners having systems in place to verify suspect and illegitimate products, and that trading partners engage in transactions only with authorized trading partners.
Storing/Accessing Transaction Data

- The law allows a dispenser to have a third party (wholesale distributor) maintain the transaction data required to be captured and stored by the pharmacy.

- Law does not require the wholesaler to do this on behalf of a pharmacy and will require a written agreement between pharmacy and wholesaler(s).

- Some wholesalers to create web-portal system for dispensers to access relevant information.

- Please note difference between access to information and storage of information.
• Phase 2
  – 10 years after enactment (November 2023), supply chain stakeholders will be required to electronically track product at the individual package level using the product identifier
  – Data shall be exchanged in a secure, interoperable, electronic manner
  – A series of assessments, public meetings, and at least one pilot program will be conducted to develop the precise requirements for, and ensure the technological feasibility of, Phase 2.
Phase II and Independent Community Pharmacy

- NCPA was able to secure significant protections for small dispensers (25 or fewer FTE) in Phase II
- Before any Phase II requirements can go into effect, HHS Secretary has to contract with a “private independent consulting firm with expertise to conduct a technology and software assessment that examines the feasibility of small dispensers conducting interoperable, electronic tracing of products at the package level. The consulting firm must agree to consult with small dispensers
- The assessment shall examine whether hardware/software is readily accessible and can be integrated into existing business practices and is not prohibitively expensive
- The Secretary shall prescribe alternative methods of compliance for small businesses to comply and a waiver process
Drug Supply Chain Security Act timeline

Prescription drug traceability

- **November 2013**
  - Enactment

- **January 1, 2015**
  - Manufacturers send and distributors receive/Th/TI/TS*
  - Manufacturers and distributors verify suspect and illegitimate product
  - Transact only with authorized trading partners
  - Dispensers** respond to requests for information

- **November 2013**
  - PDMA
  - State preemption
  - FDA guidance

- **July 1, 2015**
  - Dispensers** receive TH/TI/TS* and maintain for six years

- **2013**
  - Manufacturers serialize product
  - TH/TI/TS* electronic

- **2015**
  - Distributors transact only serialized product
  - Returns verified

- **2016**
  - Repackagers serialize product

- **2017**
  - Dispensers** transact only serialized product

- **2018**
  - Unit level traceability

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*TH/TI/TS — Transaction History/Information/Statement
**Dispensers — Under DSCSA, dispensers include retail pharmacies and hospital pharmacies; groups of chain pharmacies under common ownership and control; any person authorized by law to dispense or administer prescription drugs and affiliated warehouses or distribution centers of such entities under common ownership or control.

© 2014 Cardinal Health. All rights reserved. CARDINAL HEALTH® and ESSENTIAL TO CARE® are trademarks or registered trademarks of Cardinal Health. All other marks are the property of their respective owners. Lit. No. 10TH14-13213 (04/2014)
1. **Traceability**: Establishes a two phased national system for tracing pharmaceutical products through the supply chain.

2. **Licensing**: Establishes uniform national licensing standards for wholesale distributors and **third-party logistics providers**.

3. **Preemption**: Immediately preempts all state laws and regulations for tracing products through the supply chain (i.e., pedigree requirements) AND state laws and regulations regarding wholesale distributor and 3PL licensure.
The Act sets out seven broad categories of licensing standards for wholesale distributors and for 3PLs. These include:

- Storage and handling, maintenance of records, bond, background checks, physical inspections.
- November 2015: FDA will issue regulations to further define those standards.
- Regulations will be FINAL by November 2015 and EFFECTIVE November 2017.

This gives states two years (November 2015 to November 2017) to revise their wholesale distribution and licensing requirements to match FDA’s.
DSCSA Part 3 of 3 – Preemption

1. **Traceability**: Establishes a two phased national system for tracing pharmaceutical products through the supply chain.

2. **Licensing**: Establishes uniform national licensing standards for wholesale distributors and third-party logistics providers.

3. **Preemption**: Immediately preempts all state laws and regulations for tracing products through the supply chain (i.e., pedigree requirements); preempts state laws and regulations regarding wholesale distributor and 3PL licensure in 2017.
Pedigree preemption: As of November 2013, eighteen states had state prescription drug pedigree requirements in effect. Immediately upon enactment, the DSCSA preempted all state pedigree laws and we were be left with one standard federal solution.
Michael J. Keegan
Director, Policy and Regulatory Affairs
National Community Pharmacists Association
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Long History of ASHP Advocacy

- Gray Market
- Counterfeit Drugs
- Patient Safety
- FDA
- Technology – RFID, 2D-matrix, etc.
- Numerous ASHP policy statements
Track and Trace Law

- Enacted in 2013; along with the compounding requirements
- Goal is to track drug products throughout the supply chain!
- Creating an electronic, interoperable system over 10 years
- FDA can track product, remove suspect product
- ASHP involved throughout; communicating to Congress about Health-System concerns, and later to FDA
- Process continues with FDA
DISPENSER.—The term ‘dispenser’

“(A) means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; and

“(B) does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5).
ASHP Member Impact

“As of July 1, 2015, dispensers will be required to comply with the provisions of the DSCSA for the tracing of products through the pharmaceutical distribution supply chain.”

- Transaction history
- Transaction information
- Transaction statement
Nuts and Bolts of the Law

- Requires certain information about drug products to be passed through the supply chain
- Manufacturers → Wholesalers → Pharmacies
  - Various nuances if process involves 3PLs and direct shipment
- “Beginning not later than 4 years after the date of enactment of the Drug Supply Chain Security Act, except as provided under clause (ii), a manufacturer shall provide the transaction information, transaction history, and transaction statement required under subparagraph (A)(i) in electronic format.”
- Eventually the law requires electronic tracing of products; down to unit of use, full implementation over 10 years
ASHP Member Actions

- Review the regulations with legal/compliance counsel and ensure that appropriate health-system staff members, including pharmacy directors and technicians, information technology staff, and vendors, are familiar with the regulations and the implementation schedule.

- Establish systems for verification and handling of suspect or illegitimate product now, including quarantine procedures and reporting timeframes and requirements.

- Consult with wholesalers to determine how they can support these new and evolving requirements.

- Confer with all other non-wholesaler suppliers regarding their awareness of and readiness for implementation.
ASHP Member Actions

- Budget for implementing and sustaining a plan to create, receive, store, and retrieve the pedigree information, whether in electronic or paper format.
- Explore if a third-party provider can provide a storage and retrieval solution for the TI/TH/TS.
- Test compliance, usability, and storage of data for retrieval purposes, as all information must be maintained for six years.
- Evaluate your health system’s supply chain to hospital-owned facilities and hospital partners to determine when “business as normal” for drug distribution is within compliance as it relates to the definitions of dispensers and wholesalers.
Exceptions to the DSCSA Tracking Requirements

- Intracompany distribution of any product between members of an affiliate or within a manufacturer.
- Distribution of product between hospitals or healthcare entities under common control.
- Distribution of product for emergency reasons.
- Distribution of minimal quantities by a licensed retail pharmacy or licensed practitioner for office use.
- Distribution of intravenous product intended for fluid and electrolyte replenishment (e.g., sodium, chloride, potassium) or calories (e.g., dextrose and amino acids).
- Distribution of intravenous product used to maintain equilibrium of water and minerals in body (e.g., dialysis solution).
- Product intended for irrigation or sterile water.
- Distribution of medical gas.
ASHP Support for Members

- Seek industry consensus among members on best practices.
- Potential additional FDA guidance.
- Readiness tools and education.
- Continued advocacy as milestones approach.
Drug Supply Chain Security Act (DSCSA) – Updates and Actions for Health System Pharmacy

Tuesday, March 24, 2015, 2:00-3:00 pm ET

The DSCSA for trading partners and wholesalers has gone into effect and "dispensers" (i.e., pharmacies) will need to ensure they are prepared to manage the information received from these business partners. This webinar will provide an overview of the DSCSA and the related aspects that impact pharmacy record keeping and compliance.

Objectives:

• Describe key aspects of the DSCSA and critical dates for pharmacy.
• Provide information on actions pharmacy leaders and supply chain managers need to take.

Presenters:

Raymond Lake, R.Ph., M.S.
Corporate Director of Pharmacy Operations
MedStar Health
Baltimore, MD

Anita Ducca, M.S.
Vice President of Regulatory Affairs
HDMA
Arlington, VA

Joseph Hill, M.A.
Director, Federal Legislative Affairs
Assistant Director, Government Affairs Division
ASHP
Baltimore, MD

Track and Trace - Update and Questions for Community Members

From: David Chen
To: Pharmacy Practice Managers
Posted: Feb 10, 2015 1:00 PM
Subject: Track and Trace - Update and Questions for Community Members
Message: This message has been cross posted to the following Discussions: Inpatient Care Practitioners and Pharmacy Practice Managers.

Rollout of Federal Track-and-Trace Requirements Begins Soon

January 1 marks the start of the phased implementation of FDA’s track-and-trace regulations for manufacturers; this voluntary reporting program must be in full compliance by January 2015. This requirement is now in place in all 50 states.

A transaction is defined in the regulations as the transfer of a product between entities that results in a change of ownership. Transactions include transfers of products within an organization or its affiliates, including hospital systems.

By January 1, 2015, manufacturers will be required to maintain product tracking information for the duration of the product’s shelf life. As of January 1, a network of product tracking information must be in place to maintain product status throughout the channel of distribution.

Pharmacies that fail to meet minimum requirements by January 1 may face fines or loss of license.

According to FDA, a pharmacy may be a "dispenser" of drug products affected by the regulation as well as an authorized "vendor" or "dispenser" of other supply chain entities. For dispensing, "authorized" means having a valid license under state law.

Actions taken by other supply chain entities to ensure their compliance may require responses from dispensers and their trading partners, including pharmacies, in advance of the federal deadlines.

Continued on page 2066
Drug Supply Chain Security Act (DSCSA)

Scott Mooney
Vice President, Distribution Operations

Partnering for Better Health
Drug Quality and Security Act — DQSA

Two titles in Act address three primary topics

Title 1
Drug Compounding — Pharmacy Only

Title 2
Drug Supply Chain Security — Entire Supply Chain

• National Traceability
• Wholesaler Licensing

Act was signed by President on Nov. 27, 2013

Regulations Have Not Been Published — Penalties Not Defined
Title I: Drug Compounding

Limits Compounding to Patient Specific for Pharmacy

Creates “Outsourcing Facility” for Non-Patient Specific

Requirements for Outsourcing Facility

- Must Register with the FDA
- Direct Distribution to Practitioner or Other Dispenser
- No Third-Party Distribution
Title II: Drug Supply Chain Security

• Creates national traceability requirements
• Preempts “immediately” any/all state requirements that differ from federal language
• Begins an evolution to lot-based tracing and then to serialized item traceability during the next 10 years
  – Involves all participants in the supply chain
• Establishes federal licensure standards for wholesalers
  – Sets floor and ceiling standards the states must follow to license wholesalers
  – Creates a federal license for states that opt not to conform and license on their own
Key Requirements and Terms

- **Traceability**
- **Chain of Ownership**
- **Transaction Records**
  - Transaction History (TH)
  - Transaction Information (TI)
  - Transaction Statement (TS)
- **Direct Purchase**
- **Implementation Timeline**
- **Data Retention**
Additional requirements

• Distributors who sell product purchased direct from manufacturer, exclusive distributor or repackager who sourced direct required to send Direct Purchase Statement in lieu of:
  • Original transaction dates
  • Lot numbers

• Drop shipments required to have TI, TH and TS provided by the SHIPPER and not the distributor to the dispenser

• Saleable returns that are restocked begin their transaction history anew with the distributor and do not show that they previously had been sold and returned. Saleable returns may only be made to the immediate trading partner they came from.
Transmitting DSCSA Data

Manufacturer

Distributor

Dispenser (including practitioner)

EDI ASN

EPCIS

EDI ASN, EPCIS

PORTAL (Connect), or PAPER

Partnering for Better Health
## DSCSA Implementation Timeline

<table>
<thead>
<tr>
<th>Role</th>
<th>November 27, 2013</th>
<th>January 1, 2015</th>
<th>July 1, 2015</th>
<th>November 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Manufacturer</strong></td>
<td>State pedigree and traceability laws pre-empted</td>
<td>Must send to distributor TH — Transaction history TI — Transaction information TS — Transaction statement</td>
<td></td>
<td>• Manufacturers serialize product TH, TI, TS — electronic</td>
</tr>
<tr>
<td><strong>Distributor</strong></td>
<td>• Distributors receive TH, TI, TS</td>
<td>• Distributors ship only to authorized trading partner • Provide TH, TI, TS to dispenser • Lot # provided only for non-direct purchases</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pharmacy</strong></td>
<td>• Dispenser receives TH, TI, TS</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
## DSCSA Implementation Timeline

<table>
<thead>
<tr>
<th>Role</th>
<th>November 2018</th>
<th>November 2019</th>
<th>November 2020*</th>
<th>November 2023</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Manufacturer</strong></td>
<td></td>
<td></td>
<td></td>
<td>• Unit-level traceability for all supply chain</td>
</tr>
<tr>
<td><strong>Repackagers</strong></td>
<td>Serialize product</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| **Distributor**    | • Receive product with identifier  
                    • Receive and maintain TH, TI, TS electronically  
                    • Returns only with TI, TS |               |                |               |
| **Pharmacy**       |               |               | • Receive only product two-dimensional barcode identifiers |               |
Dispenser Obligations Near Term:

• Retention of DSCSA Transaction Data for 6 years (May be outsourced)

• System/SOP/Program for Detection and Notification of Suspicious and Illegitimate Drugs (See FDA Draft Guidance on Suspect and Illegitimate Drugs)

• Respond to FDA on Investigations within 48 hours
McKesson’s collateral serves to educate customers on DSCSA and upcoming milestones.

### Customer Education: DSCSA

The Drug Supply Chain Security Act of 2013

**What Should I Be Thinking About Now?**

- **Key Terms and Concepts**
- **Key Dates**

**Key Terms and Concepts**

- **DSCSA**
- **RxSupply**
- **RxCloud**

**Key Dates**

- **July 1, 2013**
- **November 27, 2013**
- **November 27, 2013**
- **November 27, 2015**
- **November 27, 2017**

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### Frequently Asked Questions

**DSCSA: Frequently Asked Questions**

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is DSCSA?</td>
<td>DSCSA stands for the Drug Supply Chain Security Act. It is a federal law that requires companies in the pharmaceutical supply chain to implement electronic product tracking and tracing systems.</td>
</tr>
<tr>
<td>What is RxCloud?</td>
<td>RxCloud is a McKesson platform that provides on-demand visibility and control over the drug supply chain.</td>
</tr>
<tr>
<td>What is RxSupply?</td>
<td>RxSupply is a McKesson solution that enables pharmaceutical companies to implement the drug supply chain interoperability requirements of DSCSA.</td>
</tr>
<tr>
<td>When does DSCSA go into effect?</td>
<td>DSCSA goes into effect in stages, with compliance deadlines set for manufacturers, distributors, and pharmacies. The full implementation was completed in 2017.</td>
</tr>
<tr>
<td>How can I get more information?</td>
<td>For more information, please contact your McKesson representative or visit the McKesson website.</td>
</tr>
</tbody>
</table>

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**Partnering for Better Health**
Thank You
THANKS FOR ATTENDING!

JOIN US TUESDAY, APRIL 14:
PHARMACY RESIDENTS LEADING
PRACTICE CHANGE

Questions? Contact Laura Miller at lmiller@iarx.org or 515-270-0713